Attachment 1

SEP 09 2008

Summary of Safety and Effectiveness

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h)

General Information:

Product Name:	Superopen 0.23T
Product Model:	NAM-P023A
CFR Section:	21 CFR Part 892.1000 Magnetic resonance diagnostic device
Classification Name:	System, Magnetic Resonance Imaging
Product Code:	LNH
Device Class:	Class II
Applicable Standard:	IEC60601-1, Medical electrical equipment - Part 1: General Requirements for Safety IEC60601-2-33, Medical electrical equipment – Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis 21 CFR Subchapter J, Radiological Health IEC60825-1, Safety of laser products-Part1:Equipment classification, requirement and user's guide DICOM 3.0 NEMA MS Series (MS1 – MS8)
Manufacture and Distributor:	Neusoft Medical Systems Co., Ltd. No.3-11,Wenhua Road, Heping District, Shenyang, China Post Code : 110004
Submitter:	Contact : Tianyanfang Title : Manager of Q&R Department Tel : 86-24-83660649 Fax : 86-24-83780480 E-Mail : Tianyanfang@neusoft.com Summary prepared : April 2th, 2008

Safety and Effectiveness information

Intended Uses:

The Superopen 0.23T is an imaging device, and is intended to provide the physician with physiological and clinical information obtained non-invasively and without the use of ionizing radiation. The MRI system produces transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by MRI system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

Device Description:

The Superopen 0.23T (modified) is a 0.23T permanent magnet MRI system. It is composed of Magnet and Magnet Enclosure, Gradient Coils, RF Coils, Magnet Electronics, Patient Couch, Gradient Amplifier Cabinet, Scan Cabinet, Operator Console, Intercom system.The system software based on Windows XP is an interactive program with user-friendly interface. Its functions cover scanning control, image reconstruction and image/archive management and maintenance.
The Superopen 0.23T (modified) system used the same materials, construction and operating principle as our existing marketed product, Superopen 0.23T MRI system (K062860) and Superstar 0.35T(K071154)

Predicated Device:

K062860: Superopen 0.23T
K071154: Superstar 0.35T

Statement of Substantial Equivalence:

The Superopen 0.23T (modified) system is the upgrade version of Superopen 0.23T MRI system(K062860). It is comparable and substantially equivalent to the Superopen 0.23T MRI system and Superstar 0.35T(K071154) in that they are similar in technology and intended uses. Both of these systems are open-magnet MR Imaging System, use Gradient Subsystem to provide controlled and uniform gradient magnet fields in the X, Y and Z planes, and use RF Subsystem to complete the function of RF signal transmitting/receiving and processing. Image reconstruction is controlled by console' s computer that has an interactive user interface, and the system produces 2D and 3D image that can be filmed or electronically stored for future review. Both of these systems have the traditional MRI unit.

a. Non-clinical test: The device has been evaluated for performance, biocompatibility and effectiveness as well as electrical, mechanical, chemical , biocompatibility safety and has been found to substantially equivalent to Superopen 0.23T and Superstar 0.35T.

b. Clinical test: No clinical test conducted.

Conclusion: The device was evaluated against Superopen 0.23T (K062860) and Superstar 0.35T(K071154) for all performance, safety & effectiveness requirements. According to the comparison based on the requirements of 21.CFR 807.87, we state that these devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2008

Neusoft Medical Systems Co., Ltd.
% Mr. Tamas Borsai
Division Manager, Medical Division
TÜV Rheinland of North America
12 Commerce Road
Newtown CT 06470

Re: K082485
Trade/Device Name: Superopen 0.23T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: August 22, 2008
Received: August 28, 2008

Dear Mr. Borsai:

This letter corrects our substantially equivalent letter of September 9, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

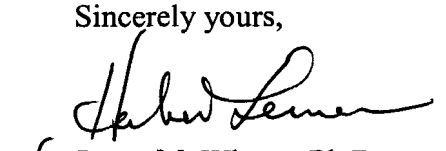
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

K082485

Neusoft 510(k)

Attachment 2

Indications for Use

510(k) Number: _____

Device Name: Superopen 0.23T

The Superopen 0.23T is an imaging device, and is intended to provide the physician with physiological and clinical information obtained non-invasively and without the use of ionizing radiation. The MRI system produces transverse, coronal, sagittal, oblique, and curved cross-sectional images that display the internal structure of the head, body, or extremities. The images produced by MRI system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.
The indications for use are as follows:

Anatomical Region: Head, Neck, Shoulder, Breast, Wrist, Ankle, Body, Spine, Knee, Extremities
Nucleus excited: Proton
Diagnostic uses: T1,T2, proton density weighted imaging
Diffusion weighted imaging
MR Angiography
Imaging processing
Imaging capabilities: 2D, 3D Spin Echo(SE)
Turbo spin echo (TSE)
Short time inversion recovery (STIR); Fast STIR, IRFFE,
IRSE, Fast IR, IR TSE
Fluid attenuated inversion recovery (FLAIR); Fast FLAIR
2D,3D Fast Field Echo (FFE)
T1/T2/N-Fast field echo (FFE);
N-Fast filed echo 3D; T1-Fast field echo 3D;
Dual echo (DE);DTSE; DSE;
MR angiography FE, FFE 3D;
Echo Planar Imaging (EPI)

Prescription Use: YES (Part 21 CFR 801 Subpart D)

Over-The-Counter Use: NO (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF DEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K082485